For Immediate Release

Contact: Craig Orfield
(202) 224-6770

Monday, April 30, 2007

SENATE SET TO DEBATE KEY DRUG SAFETY BILL

Washington D.C. – U.S. Senator Mike Enzi, R-WY, Ranking Member of the Senate Health, Education, Labor and Pensions Committee (HELP Committee), today said that the Senate has an opportunity to approve a bill to clarify and strengthen the Food and Drug Administration's (FDA) authority and give it new tools to take measured and appropriate steps to protect the health and safety of all Americans, as the Senate begins to debate drug safety on the floor.

"The Food and Drug Administration Revitalization Act, which we will be discussing this week on the Senate floor, is a comprehensive bill to enhance drug safety, provide key resources to review new drugs and medical devices, and ensure that drugs and devices for children are safe and effective," Enzi said. "I look forward to an informative and thorough debate on this critical legislation"

"Imagine a system that gives the FDA, through sound science and remarkable innovation, the tools to get drugs to the market quickly and efficiently, especially when lives are on the line and people need new drugs and therapies," Enzi said. "Imagine also a system that gives the FDA new authority to take swift, appropriate, and decisive action to ensure patient safety and protect consumers when new information comes to light to expose unexpected risks. We can make this a reality."

"We have the opportunity this week to renew key FDA programs, and to ensure that the FDA continues to operate with new tools to ensure that safety is forefront of every decision during the life of a drug."

The bill being brought to the floor today represents over a year of bipartisan discussions and cooperation following the Vioxx incident. It establishes a system of active surveillance for drugs already on the market, and explicitly gives the FDA new authority through Risk Evaluation and Mitigation Strategies (REMS) to respond quickly and appropriately when previously unknown risks arise.

"Many people are asking, 'Why REMS? Why now?'" Enzi said. "The answer is easy. Right now, the FDA has its hands tied behind its back when it tries to manage the risks of drugs already on the market. This bill will give FDA new tools to act when the agency's post-market surveillance signals potential dangers from a drug or therapy.

Pulling a drug from the market and denying patients who need it shouldn't be the only tool available to the FDA."

"The authority of the Food and Drug Administration (FDA) touches the lives of all Americans – from infants to the elderly, animals that provide the food and fiber for living, and even our pets," Enzi said. "We need to restore peace of mind for Americans who are buying drugs for themselves and their children."

####

Restoring public trust and confidence in the FDA

S.1082: The Food and Drug Administration Revitalization Act

From infants to the elderly, this legislation helps ensure the drugs we buy are safe and effective.

The legislation establishes routine surveillance for drug safety for drugs already on the market. A new surveillance system will identify and assess risks for all drugs. This system, along with clear drug labeling, will help better manage risk for most drugs. However, some drugs will need additional tools to manage serious risks, and FDA will now be able to require and approve a risk evaluation and mitigation strategy (REMS) for these drugs. Sponsors would propose a risk management strategy, and FDA would approve it after structured negotiations.

For those drugs that have a REMS, it will always include FDA-approved professional labeling and a timetable for periodic assessment of the REMS. It may also include REMS tools to assess or manage risks. For example, FDA can require a drug-specific study when the surveillance system isn't sufficient to assess a serious risk. A REMS would be assessed in response to new information about a serious risk, and could be modified in response to new information.

To boost enrollment and track the progress of clinical trials, the data bank at ClinicalTrials.gov will be expanded under this legislation. Currently, only clinical trials of drugs for serious and life threatening conditions are required to register in the data bank. Patients and providers will have the most up-to-date information because results information may be added to this database.

Prescription Drug User Fees

The legislation codifies the user fee agreement reached by drug and biotech industries with the FDA. It establishes an overall amount for user fees (nearly $393 million for 2008), and expands user fees for post-approval drug safety programs. The legislation also includes the FDA-industry proposal to create a voluntary user fee program under which drug companies can submit direct-to-consumer television advertisements to the agency for review before they are distributed.

Medical Device User Fees
The legislation reflects the agreement between FDA and industry for reauthorizing device user fees. The agreement establishes an overall amount of $287 million in user fees over five years, with $48 million in 2008. This is coupled with a fixed 8.5% annual increase and further reduction of fees for small business.

To make this program work more efficiently, the legislation includes an FDA-industry proposal to modify the current third party inspection program. Provisions to clarify that device establishments can register and list products electronically should increase FDA's efficiency.

Protecting our children: keeping pediatric medical products safe

Best Pharmaceuticals for Children
The legislation reauthorizes the Best Pharmaceuticals for Children Act (BPCA), which helps ensure that children's drugs are safe. BPCA generally provides six months of additional exclusivity to drug manufactures to encourage safety studies of drugs in children. Only three months of additional exclusivity are offered if US sales of the active moiety by the innovator and its affiliates exceed $1 billion annually at the time FDA's written request for study is issued.

Pediatric Research Improvement
The legislation reauthorizes the Pediatric Research Equity Act (PRIA) and improves the law to make it more effective at ensuring that drugs for children are safe.

To improve coordination with the *Best Pharmaceuticals for Children Act (BPCA)*, PRIA would consolidate an internal FDA committee to review issues of pediatric-related labeling and assessments. Doing so ensures that a drug that falls under PRIA or BPCA is reviewed by both experts for that particular drug and those with pediatric expertise. If a company chooses not to pursue pediatric exclusivity for an already marketed drug under BPCA, and no study is performed through NIH, the Secretary has the authority to require the submission of pediatric data for such drug.

Given the interaction between BPCA and PRIA, the legislation clarifies that those programs will continue to operate together with a five year authorization period for both programs.

Pediatric Medical Devices
This proposal allows profit for approved devices specifically designed to meet a pediatric need. It maintains existing requirement that a humanitarian use device is limited to one that treats and diagnoses diseases or conditions that affect fewer than 4,000 individuals in the U.S. per year. Profit is allowed for up to 4,000 pediatric devices.

The legislation encourages pediatric device development, manufacture and distribution by tracking results and providing grants. The bill grants authority to the FDA's Pediatric

Advisory Committee to monitor pediatric devices and make recommendations for improving their availability and safety. Post-market surveillance of medical devices used in children is improved, and public access to post-market studies of pediatric medical devices is expanded.

####